

UNITED STATES DISTRICT COURT
FOR THE
DISTRICT OF MASSACHUSETTS

_____)	
JOHN HANCOCK LIFE INSURANCE)	
COMPANY, JOHN HANCOCK)	
VARIABLE LIFE INSURANCE)	
COMPANY, and MANULIFE INSURANCE)	
COMPANY (f/k/a INVESTORS)	
PARTNER LIFE INSURANCE)	
COMPANY),)	CIVIL ACTION NO. 05-11150-DPW
)	
Plaintiffs,)	
)	
v.)	
)	
ABBOTT LABORATORIES,)	
)	
Defendant.)	
_____)	

JOHN HANCOCK'S OBJECTIONS
TO THE AFFIDAVIT OF JEANNE M. FOX

Plaintiffs John Hancock Life Insurance Company, John Hancock Variable Life Insurance Company and Manulife Insurance Company (collectively, "John Hancock" or "Hancock") object to the introduction into evidence of paragraphs 10, 11, 14 and 23 of the Affidavit of Jeanne M. Fox (the "Fox Affidavit") on the grounds that they constitute hearsay not within any exception contained in Fed. R. Evid. 803 and 804. Hancock objects to paragraph 19 because it contains impermissible opinion testimony by a lay witness, in violation of Fed. R. Evid. 701.

Ms. Fox should not be permitted to testify in paragraphs 10, 11, 14 and 23 of her affidavit to the out-of-court statements of FDA officials for the truth of the matter asserted within those statements. Such testimony is inherently unreliable and should be excluded.

In paragraph 10, Ms. Fox states that “It was my understanding, based on my participation in discussions with the FDA, that the FDA’s concern about the potential for QT prolongation was not based on any data regarding...ABT-773.” She is offering the statements regarding QT prolongation made by FDA officials to prove that they were not concerned about ABT-773’s potential for QT prolongation. This is demonstrably hearsay outside of any exception, and should not be allowed by the Court.

At paragraph 11, Ms. Fox testifies regarding an FDA meeting where liver toxicity issues were discussed. She states that she “came away from this conference with the impression that the FDA was saying that it didn’t have all the answers....” Ms. Fox may not testify to her impression of what FDA officials said at a meeting in 2001. These out-of-court statements are being offered to prove the course being charted by the FDA to address liver-toxicity issues. Ms. Fox’s after-the-fact impression of the purported statements of FDA officials lack sufficient indicia of reliability and should not be admitted.

Similarly, at paragraph 14, Ms. Fox discusses an ABT-773 dog toxicology study. She testifies that “[t]he FDA representatives informed us that they were requesting this additional study based on certain information that they were not at liberty to share.” This, too, is hearsay that falls beyond any exception. These out-of-court statements of FDA representatives state that a dog toxicology study was requested by the FDA, and are offered to prove the same. The statements should therefore be excluded from the Fox Affidavit.

Ms. Fox seeks to introduce the out-of-court statements contained in a Health News Daily Article (D's Exhibit AC) to prove the very subject of the new article – the FDA's desire for QT prolongation data. As in the instances described above, the news article is an out-of-court statement that is offered to prove its truth. Ms. Fox should therefore be precluded from testifying to its contents.

Hancock objects to the following statement by Ms. Fox in paragraph 19 regarding the FDA's pediatric rule: "If the sponsor obtains a waiver from the FDA or a deferral to allow it to complete development of the product for children at a later time, the FDA would approve an adult formulation of the drug without requiring the sponsor to complete the pediatric development by the time the adult product is approved." The statement is opinion testimony by a lay witness which is impermissible under Fed. R. Evid. 701. Ms. Fox is not testifying as an expert in this case, and thus may not offer her opinion on what is required for a waiver of the FDA's pediatric rule. The testimony should therefore not be admitted.

With regard to the exhibits attached to the Affidavit of Jeanne M. Fox, Hancock incorporates by reference the objections stated in Hancock's Objections to Abbott's Proposed Trial Exhibits.

Conclusion

For the foregoing reasons, John Hancock respectfully requests that the Court not admit the above noted portions of the Fox Affidavit.

Respectfully submitted,

JOHN HANCOCK LIFE INSURANCE
COMPANY, JOHN HANCOCK VARIABLE
LIFE INSURANCE COMPANY and
MANULIFE INSURANCE COMPANY
By their attorneys,

/s/ Brian A. Davis

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Date: March 9, 2008

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and that paper copies will be sent to those non-registered participants (if any) on March 9, 2008.

/s/ Richard C. Abati

Richard C. Abati